

HARNES, DICKEY & PIERCE, P.L.C.

ATTORNEYS AND COUNSELORS

P O BOX 828

BLOOMFIELD HILLS MICHIGAN 48303

U S A

CABLE
PATENTS TROYM CH GAN

TELEX NO & R F I Y

28/637 HARNES UP

TELEFACSIMILE

(248) 641 0270

10380 U.S. PTO



OR COURIER DELIVERY ONLY
5445 CORP PARK DRIVE
BLOOMFIELD HILLS MICHIGAN 48303
(248) 641 1600

03/31/98

March 31, 1998

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

EXPRESS MAILING CERTIFICATE

Applicant: **HONGWEI ZHAO**

For: Patent Application - **APPARATUS AND METHOD FOR GENERATING
CHANGES IN A MAMMALIAN
ORAL/THROAT CAVITY**

Attorney Docket No. **5203-000001**

Attorney: **Gordon K. Harris, Jr.**

"Express Mail" Mailing Label Number **EH962831997 US**

Date of Deposit..... March 31, 1998

I hereby certify that a transmittal letter (3 pages); patent application (13 pages), executed Declaration and Power of Attorney (2 pages); Verified Statement (Declaration) Claiming Small Entity Status - Independent Inventor; 3 sheets of Formal Drawings; Information Disclosure Statement (4 pages); Form 1449 (1 page) with 1 reference (2 pages); and a check in the amount of \$436.00 are being deposited with the United States Postal Service "Express Mail Post Office To Addressee" service under 37 C.F.R. 1.53(b) on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

March 31, 1998
Dated

Joan Oleksa

NEW, CONTINUATION, DIVISIONAL OR
CONTINUATION-IN-PART APPLICATION
UNDER 37 C.F.R. §1.53(b)

Attorney Docket No. 5203-000001

Express Mail Label No. EH 962 831 997 US

Date March 31, 1998



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Commissioner of Patents and Trademarks
Washington, D. C. 20231

Sir:

Transmitted herewith for filing under 37 C.F.R §1.53(b) is a patent application for

**APPARATUS AND METHOD FOR GENERATING PRESSURE CHANGES IN
A MAMMALIAN ORAL/THROAT CAVITY**

identified by: ☐ First named inventor _____
or ☒ Attorney Docket No. (see above)

1. Type of Application

☒ This application is a new (non-continuing) application.

☐ This application is a ☐ continuation / ☐ divisional / ☐ continuation-in-part of prior application No. _____. Amend the specification by inserting before the first line the sentence:

--This is a [continuation/division/continuation-in-part] of United States patent application No. _____, filed _____--

☐ The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied, is considered part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

If for some reason applicant has not requested a sufficient extension of time in the parent application, and/or has not paid a sufficient fee for any necessary response in the parent application and/or for the extension of time necessary to prevent the abandonment of the parent application prior to the filing of this application, please consider this as a Request for an Extension for the required time period and/or authorization to charge our Deposit Account No. 08-0750 for any fee that may be due. THIS FORM IS BEING FILED IN TRIPLICATE: one copy for this application; one copy for use in connection with the Deposit Account (if applicable); and one copy for the above-mentioned parent application (if any extension of time is necessary).

2. Contents of Application

a. Specification of **13** pages;

- ☐ A microfiche computer program (Appendix);
☐ A nucleotide and/or amino acid sequence submission;

☐ Because the enclosed application is in a non-English language, a verified English translation ☐ is enclosed ☐ will be filed.

☐ Cancel original claims _____ of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing date purposes.)

b. ☒ Drawings on **3** sheets;

Attorney Docket No 5203-000001
Express Mail Label No EH 962 831 997 US
Date March 31, 1998

- c. ☐ A signed Oath/Declaration ☒ is enclosed / ☐ will be filed in accordance with 37 C.F.R. §1.53(f).

The enclosed Oath/Declaration is ☒ newly executed / ☐ a copy from a prior application under 37 C.F.R. §1.63(d) / ☐ accompanied by a statement requesting the deletion of person(s) not inventors in the continuing application.

d. **Fees**

| FILING FEE | Number | Number | | Basic Fee |
|------------------------------------------------------------------------------------------|-----------|--------|------------|-----------------|
| CALCULATION | Filed | Extra | Rate | \$790.00 |
| Total Claims | 12 - 20 = | × | \$22.00 = | -0- |
| Independent Claims | 4 - 3 = | 1 × | \$82.00 = | \$82.00 |
| Multiple Dependent Claim(s) Used | | | \$270.00 = | |
| FILING FEE - NON-SMALL ENTITY | | | | \$872.00 |
| FILING FEE - SMALL ENTITY: Reduction by 1/2 | | | | |
| <input checked="" type="checkbox"/> Verified Statement under 37 C.F.R. §1.27 is enclosed | | | | \$436.00 |
| <input type="checkbox"/> Verified Statement filed in prior application. | | | | |
| Assignment Recordal Fee (\$40.00) | | | | |
| 37 C.F.R. §1.17(k) Fee (non-English application) | | | | |
| TOTAL | | | | \$436.00 |

- ☒ A check is enclosed to cover the calculated fees. The Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 08-0750. A duplicate copy of this document is enclosed.

- ☐ The calculated fees will be paid within the time allotted for completion of the filing requirements.

- ☐ The calculated fees are to be charged to Deposit Account No. 08-0750. The Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to said Deposit Account. A duplicate copy of this document is enclosed.

3. **Priority Information**

- ☐ **Foreign Priority:** Priority based on _____ Application No. _____, filed _____, is claimed.

- ☐ A copy of the above referenced priority document ☐ is enclosed / ☐ will be filed in due course, pursuant to 35 U.S.C. §119(a)-(d).

- ☐ **Provisional Application Priority:** Priority based on United States Provisional Application No. _____, filed _____, is claimed under 35 U.S.C. §119(e).

Attorney Docket No 5203-000001

Express Mail Label No. EH 962 831 997 US

Date March 31, 1998

4 Other Submissions

☐ A Preliminary Amendment is enclosed.

☒ An Information Disclosure Statement, 1 sheets of PTO Form 1449, and 1 publication document is are enclosed.

☒ A power of attorney

☒ is submitted ☒ with the new Declaration.

☐ is of record in the prior application and ☐ is in the original papers / ☐ a copy is enclosed.

☐ An Assignment of the invention

☐ is enclosed with a cover sheet pursuant to 37 C.F.R. §§3.11, 3.28 and 3.31.

☐ is of record in a prior application. The assignment is to _____, and is recorded at Reel _____, Frame(s) _____.

☐ An Establishment of Assignee's Right To Prosecute Application Under 37 C.F.R. §3.73(b), and Power Of Attorney is enclosed.

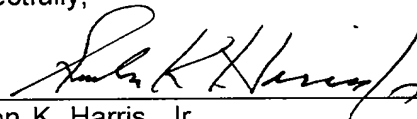
☒ An Express Mailing Certificate is enclosed.

☐ Other: _____

Attention is directed to the fact that the correspondence address for this application is:

Harness, Dickey & Pierce, P.L.C.
P.O. Box 828
Bloomfield Hills, Michigan 48303
(248) 641-1600.

Respectfully,



Gordon K. Harris, Jr.
Reg. No. **28,615**

Date March 30, 1998
Harness, Dickey & Pierce, P.L.C.
P.O. Box 828
Bloomfield Hills, Michigan 48303
(248) 641-1600

**APPARATUS AND METHOD FOR GENERATING PRESSURE CHANGES
IN A MAMMALIAN ORAL/THROAT CAVITY**

FIELD OF THE INVENTION

5 This invention relates generally to methodology and apparatus for establishing predetermined vacuum or pressure levels in the mouth and throat cavity of a mammalian body, such as that of a human, in coordination with the mammal's respiratory pattern.

BACKGROUND OF THE INVENTION

10 This invention is based on my discovery that respiration-regulated air pressure, either positive or negative (vacuum), in a person's mouth and throat cavity, produces beneficial effects to the person's health such as alleviation of throat discomfort and snoring. The hypothetical explanation of this finding is that respiration-regulated air pressure in a person's mouth and throat cavity stimulate the body's autonomic nervous system, circulatory system, and especially lymphatic system and therefore enhances
15 certain physiological functions, such as lymphatic flow. The body's autonomic nervous system, circulatory system, and lymphatic system are all responsive to pressure changes in the respiration system while a person is inhaling and exhaling. For example, J.W. Shields has conducted a study on the effects of breathing on the lymphatic system. Using cameras inside the body, he found that deep, diaphragmatic breathing stimulated
20 the cleansing of the lymph system by creating a vacuum effect which draws lymph through the bloodstream. See *Human Central Lymph Propulsion*, JAMA, Vol. 246, No. 18, Nov. 6, 1981, Shields, et al.

Summary of the Invention

Accordingly, in one aspect of the invention, a method for inducing pressure changes in the mouth and throat cavity of a mammal includes the steps of monitoring a respiration pattern of the mammal to determine a first time period during which the mammal is inhaling and a second time period during which the mammal is exhaling. A partial vacuum is induced in the mammal's mouth and throat cavity during the first time period and the partial vacuum is removed during the second time period.

In another aspect of the invention apparatus for inducing pressure changes in the mouth and throat cavity of a mammal includes a regulated vacuum source having an outlet and a control input, an appliance in fluid communication with the outlet of the vacuum source, the appliance adapted for placement in a mouth of a mammal so as to be in fluid communication therewith. A sensor, adapted to be coupled at a preselected portion of the mammal's anatomy and operative to generate a first signal whenever the mammal inhales and a second signal whenever the mammal exhales, signals a controller having an output coupled for controlling the output of the vacuum source. The controller has at least one input coupled for receipt of the first and second signals from the sensor. The controller is operative upon receipt of the first signal to cause the vacuum source to pull at least a partial vacuum in the appliance. The controller is operative upon receipt of the second signal to cause removal of the partial vacuum from the appliance.

BRIEF DESCRIPTION OF THE DRAWINGS

The objects and features of the invention will become apparent from a reading of a detailed description taken in conjunction with the drawings, in which:

FIG. 1 is a functional block diagram of a first embodiment of a system arranged in accordance with the principles of the invention;

FIG. 2 is a functional schematic of sensor element suitable for use in the system of FIG. 1;

FIGS. 3A and 3B are side and top cross sectional views of an oral appliance arranged in accordance with the principles of the invention;

5 FIG. 4 is a timing diagram showing the output of sensor 144 of FIG. 1 in relation to a typical respiratory pattern; and

FIG. 5 is a functional block diagram of an alternative embodiment of the invention.

DETAILED DESCRIPTION

10 FIG. 1 sets forth a functional diagram of apparatus arranged in accordance with the invention. System 100 includes a vacuum source or pump 110 having an outlet 112 coupled to a first end of a conduit 182. An opposite end of conduit 182 is coupled to an inlet of regulator 180. An output of regulator 180 is coupled via conduit 172 to a vacuum chamber 170. Chamber 170 is coupled via conduit 163 to a first port 162a of
15 fluid flow valve or fluid switch 160. A second port 162b of switch 160 is vented to the atmosphere via conduit 161. Port 162c of switch 160 is coupled via a preferably flexible conduit 125 to an inlet port 122 of oral appliance or appliance element 120 which is sized and shaped for facile insertion into the mouth of an individual.

20 Appliance 120 is substantially disk shaped and has a hollow interior 132 in fluid communication with the conduit 125 via appliance inlet 122. Additionally a plurality of passages 126, 128 and 130 are arranged in a preselected pattern on at least one side of appliance 120 for providing fluid communication between interior 132 of appliance 120 and the mouth and throat cavity of the individual.

Sensor 140, for generating an indication of whether or not the individual is inhaling or exhaling, includes a belt 142 for engagingly surrounding the abdominal cavity of the user. Ends of the belt 142 terminate at a sensor element 144 which is operative to generate signals indicating inhaling and exhaling. The signals are coupled
5 via bus 146 to an input 154 of a controller 150. Controller 150 may, for example, take the form of a stored program type controller such as a microprocessor-based element. Output 152 of controller 150 is coupled via bus 155 to a control input 181 of regulator 180. A second output 153 of controller 150 is coupled via bus 156 to a control input 164 of fluid switch 160.

10 In operation, system 100 generates desired pressure levels by having the individual utilizing the system insert the appliance 120 into the oral cavity and by strapping belt 142 about the individual's abdominal cavity. Upon inhaling in the midst of a normal breathing pattern, an appropriate signal is developed by sensor 144 and coupled to controller 150. Controller 150, via bus 155, enables regulator 180 to
15 regulate the output 112 of vacuum source 110 at a preselected vacuum level. Upon receipt of the inhaling indication signal, controller 150 signals switch 160 via bus 156 to fluidly couple port 162a to port 162c thereby enabling at least a partial vacuum to be pulled at the interior 132 of appliance 120 via conduit 125. This partial vacuum is extended into the mouth and throat cavity via passages 126, 128 and 130. Upon
20 cessation of the inhaling cycle and initiation of the exhaling cycle of the breathing pattern, an appropriate signal at sensor 144 is coupled to controller 150 which signals switch 160 via bus 156 to switch port 162c from its fluid connection to port 162a over to port 162b, thereby venting conduit 125 and appliance 120 to the atmosphere via conduit 161. It has been found that a coordinated application of such a vacuum
25 pressure to an individual during the inhalation process produces beneficial results such as alleviation of throat discomfort.

Vessel 170 serves dual functions of 1) acting as an intermediate vacuum chamber and 2) collecting any liquid which is inadvertently entrained in the air fluid flow in the conduit system .

One example of sensor 144 of the system of FIG. 1 is set forth in further detail in the diagram of FIG. 2. Sensor 144 includes a variable impedance element such as a variable resistor 210 having a fixed terminal 212 coupled to a first end 143a of belt 142 and movable terminal 214 coupled to a second end 143b of belt 142.

Additionally attached between the first terminal 212 and second terminal 214 of resistor 210 is a return bias spring 220.

The value of the variable resistance exhibited between terminals 212 and 214 is coupled to input 154 of controller 150 via leads 172a and 172b of bus 172.

As seen from the details of FIG. 2, when the individual wearing belt 142 inhales, the abdominal cavity expands which pulls ends 143a and 143b of belt 142 further apart. This movement, in turn, causes the wiper or movable terminal 214 of resistor 210 to move toward the right as seen in the view of FIG. 2, thus exhibiting a positive change in the resistance presented to terminals 172a and 172b of bus 172. Conversely, when the inhalation period ends and exhalation begins, then the user's abdominal cavity will contract and the return spring element 220 will pull the movable terminal 214 back toward the rest position or to the left as shown in FIG. 2. Hence, during this cycle a negative resistance change is exhibited at terminals 172a and 172b.

These positive and negative electrical resistance value changes are monitored by the controller 150. For example, a microprocessor could be programmed to sample the electrical resistance presented via bus 172 ten times per second. The controller would enter a working condition after five stable cycles of breathing pattern were established.

5 At this point, the controller would enable the vacuum pump 110 via regulator 180 only when controller 150 observes a positive change in resistance at input 154 of controller 150.

The timing diagram of Fig. 5 sets forth the change in resistive impedance exhibited by sensor 144 along axis 506 versus time along axis 507. Controller 150

10 enters a working routine after recognizing a predetermined number (e.g. 10) of stable or constant respiration pattern cycles.

During expiration phase 501, the sensor's resistance change is negative which leads to action by controller 150 to inhibit the pulling of a partial vacuum in oral appliance 120. In transition phase 502 where no resistance changes are observed,

15 controller 150 continues inhibiting the pulling of a partial vacuum in appliance 120. However, if controller 150 determines that phase 502 has extended for a time period indicating abnormality of the breathing pattern, such as is found during sleep apnea, controller 150 may initiate re-application of partial vacuum prior to the end of phase 502. During inspiration phase 503, controller 150 enables the pulling of a partial

20 vacuum at appliance 120. This pattern will continue for so long as a stable breathing pattern of predetermined minimum length is maintained. A stable breathing pattern may be defined as one exhibiting not only a steady overall breathing cycle time 505, but also having intermediate periods 502 and 504, which are of predetermined minimum durations wherein neither inhalation nor expiration are occurring.

Further details of appliance 120 and associated mouth cover 400 are set forth in Figs. 3A, 3B and 4. Opening 130 of Fig. 1 preferably, as shown in Fig. 3B comprises a plurality of openings at an end of appliance 120 positioned furthest inward of the mammal's oral cavity.

5 Mouth cover 400 of Figs. 3A, and 3B may take a variety of contoured shapes suitable for comfortable and leakless coupling of the partial vacuum to interior 132 of appliance 120 via conduit 121. Holes 410 and 420 in cover 400 are provided for receipt of a strap (not shown) which would encircle the patient's head to keep the mouth cover in place.

10 An additional embodiment of the invention is set forth in the functional block diagram of FIG. 5. The arrangement of FIG. 5 has many common features with the system of FIG. 1, but with the addition of a positive or pressurized supply of air for application to the oral/throat cavity during expiration periods.

15 In the system of FIG. 5, the human or mammalian body 500 has an appropriately coupled respiration sensor 544 and an oral appliance 520. A programmed controlling unit 550 is coupled for receipt of signals from the respiration sensor 544. Controlling unit 550 sets the flow position of a flow valve or switch 560 and can additionally set predetermined levels of vacuum and pressurized air via controlling unit outputs coupled to a first pressure regulator 580a and a second pressure regulator 580b.

20 Regulator 580a controls the vacuum level in chamber 570a which is evacuated by a vacuum air source 510. Pressure regulator 580b controls the pressure level in chamber 570b which is supplied from a pressurized air source 590.

Flow valve or switch 560, under the control of unit 550, applies either a predetermined vacuum level or a predetermined air pressure to the body's oral cavity via appliance 520.

5 In operation, this system, in addition to applying at least a partial vacuum during periods of inspiration, additionally applies positive pressure via the oral appliance during periods of expiration.

10 The invention has been described with reference to an exemplary embodiment solely for the sake of example. Those skilled in the art will recognize that variations can be made to this specific example. The scope and spirit of the invention is defined by the appended claims.

I CLAIM:

1. A method for inducing pressure changes in a mouth and throat cavity of a mammal comprising the steps of:

monitoring a respiration pattern of the mammal to determine a first time period during which the mammal is inhaling and a second time period during which the mammal is exhaling;

inducing at least a partial vacuum in the mammal's mouth and throat during the first time period; and

removing the at least partial vacuum during the second time period.

2. Apparatus for inducing pressure changes in a mouth and throat cavity of a mammal, the apparatus comprising:

a vacuum source having a controlled output;

an appliance in fluid communication with the controlled output of the vacuum source, the appliance adapted for placement in a mouth of a mammal so as to be in fluid communication therewith;

a sensor adapted to be coupled to a preselected portion of the mammal's anatomy and operative to generate a first signal whenever the mammal inhales and a second signal whenever the mammal exhales;

a controller having an output coupled to the controlled output of the vacuum source, and at least one input coupled for receipt of the first and second signals, the controller operative, upon receipt of the first signal, to cause the controlled output to pull at least a partial vacuum in the appliance, and the controller operative, upon receipt of the second signal, to cause the controlled output to cease pulling the at least partial vacuum.

3. The apparatus of Claim 2 wherein the appliance comprises a conduit having a first end coupled to the controlled output of the vacuum source and a second end adapted for insertion into the mouth of the mammal.

4. The apparatus of Claim 3 wherein the appliance further comprises an appliance coupled to the second end of the conduit and shaped for receipt by the mouth of the mammal, the appliance including at least one opening enabling fluid communication between the conduit and at least a portion of the mouth.

5. The apparatus of Claim 4 wherein the appliance includes a plurality of openings arranged in a predetermined pattern, the plurality of openings enabling the fluid communication between the conduit and at least a portion of the mouth.

6. The apparatus of Claim 2 wherein the sensor comprises a variable electrical impedance element coupled to the mammal's anatomy in a manner such that the impedance element exhibits a first impedance value change whenever the mammal is inhaling and a second impedance value change whenever the mammal is exhaling.

7. The apparatus of Claim 6 wherein the sensor further comprises a belt having first and second ends, the belt adapted for placement around an abdominal cavity of the mammal, and wherein the variable electrical impedance element comprises a variable resistor having a fixed terminal coupled to the first end of the belt and a movable terminal coupled to the second end of the belt.

8. The apparatus of Claim 7 further comprising a return spring coupled between the fixed and movable terminals of the variable resistor.

9. Apparatus for inducing pressure changes in a mouth and throat cavity of a mammal, the apparatus comprising:

a regulated vacuum source having a controlled output;

5 a fluid switch having first, second and third ports, the first port coupled in fluid communication with the controlled output, and the second port coupled in fluid communication with ambient atmosphere;

an appliance in fluid communication with the third port of the fluid switch, the appliance adapted for placement in a mouth of a mammal so as to be in fluid communication therewith;

10 a sensor adapted to be coupled to a preselected portion of the mammal's anatomy and operative to generate a first signal whenever the mammal inhales and a second signal whenever the mammal exhales;

15 a controller having an output coupled to the fluid switch and having at least one input coupled for receipt of the first and second signals, the controller operative, upon receipt of the first signal, to cause the fluid switch to fluidly couple the first port to the third port, and the controller operative, upon receipt of the second signal, to cause the fluid switch to fluidly couple the second port to the third port.

10. The method of Claim 1 further comprising the step of inducing a positive pressure in the mammal's mouth during the second time period.

20 11. The method of Claim 1 wherein the step of removing includes applying atmospheric pressure in the mammal's mouth.

12. Apparatus for inducing pressure changes in a mouth and throat cavity of a mammal, the apparatus comprising:

a regulated vacuum source having a controlled vacuum output;

5 a regulated pressurized air source having a controlled pressurized air output;

a fluid switch having first, second and third ports, the first port coupled in fluid communication with the controlled vacuum output and the second port coupled in fluid communication with the pressurized air output;

10 an appliance in fluid communication with the third port of the fluid switch, the appliance adapted for placement in a mouth of a mammal so as to be in fluid communication therewith;

a sensor adapted to be coupled to a preselected portion of the mammal's anatomy and operative to generate a first signal whenever the mammal inhales and a second signal whenever the mammal exhales;

15 a controller having an output coupled to the fluid switch and having at least one input coupled for receipt of the first and second signals, the controller operative, upon receipt of the first signal, to cause the fluid switch to fluidly couple the first port to the third port, and the controller operative, upon receipt of the second signal, to cause the fluid switch to fluidly couple the second port to the third port.
20

APPARATUS AND METHOD FOR GENERATING PRESSURE CHANGES IN A MAMMALIAN ORAL/THROAT CAVITY

ABSTRACT

Predetermined pressure changes in the oral and throat cavity is achieved by inducing at least a partial vacuum in the mouth and throat area of a mammal in temporal coordination with the mammal's breathing pattern. The partial vacuum is selectively applied to the mouth and throat cavity only during inhalation cycles of the breathing pattern. A further aspect of the invention provides for additionally inducing a positive or atmospheric pressure in the mouth and throat cavity only during exhalation cycles of the breathing pattern.

5

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

APPARATUS AND METHOD FOR GENERATING PRESSURE CHANGES IN A MAMMALIAN ORAL/THROAT CAVITY

the specification of which (check one)

☒ [X] is attached hereto.

☐ [] was filed on _____ as Application
Serial No. _____ and was amended on
_____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, section 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN APPLICATION(S)

| | | | <u>Priority Claim</u> | |
|----------|-----------|------------------------|-----------------------|-------|
| (Number) | (Country) | (Day/Month/Year filed) | Yes | No |
| _____ | _____ | _____ | _____ | _____ |
| (Number) | (Country) | (Day/Month/Year filed) | Yes | No |
| _____ | _____ | _____ | _____ | _____ |
| (Number) | (Country) | (Day/Month/Year filed) | Yes | No |
| _____ | _____ | _____ | _____ | _____ |

DECLARATION AND POWER OF ATTORNEY

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States Provisional application(s) listed below:

PRIOR PROVISIONAL APPLICATIONS

(application serial number)

(Month / Day / Year filed)

(application serial number)

(Month / Day / Year filed)

I hereby claim the benefit under Title 35, United States Code, section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, section 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

| Application Serial No. | Filing Date | Status - patented, pending, abandoned |
|------------------------|-------------|------------------------------------------|
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint **Gordon K. Harris, Jr.**, Reg. No. **28,615**, and each principal, attorney of counsel, associate and employee of Harness, Dickey & Pierce, P.L.C., who is a registered Patent Attorney, my attorney with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith. I request the Patent and Trademark Office to direct all correspondence and telephone calls relative to this application to Harness, Dickey & Pierce, P.L.C., P. O. Box 828, Bloomfield Hills, Michigan 48303 (248) 641-1600.

Full name of sole or first inventor: Hongwei Zhao

Inventor's signature: Hongwei Zhao

Date: March 27, 1998

Residence: 977 Thompson Blvd., Windsor Ontario N8S 2G7 CANADA

Citizenship: People's Republic of China

Post Office Address: (same)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit:

Examiner:

Inventor(s):

Serial Number:

Filed:

For: **APPARATUS AND METHOD FOR GENERATING PRESSURE CHANGES
IN A MAMMALIAN ORAL/THROAT CAVITY**

Patent No.

Issued:

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) AND 1.27(b)) - INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention described in

☒ [X] the specification filed herewith.

☐ [] the application whose serial number is set forth above.

☐ [] the patent set forth above.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not likewise be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Signature Hongwei Zhao
(Typed Name) Hongwei Zhao

Date March 27, 1998

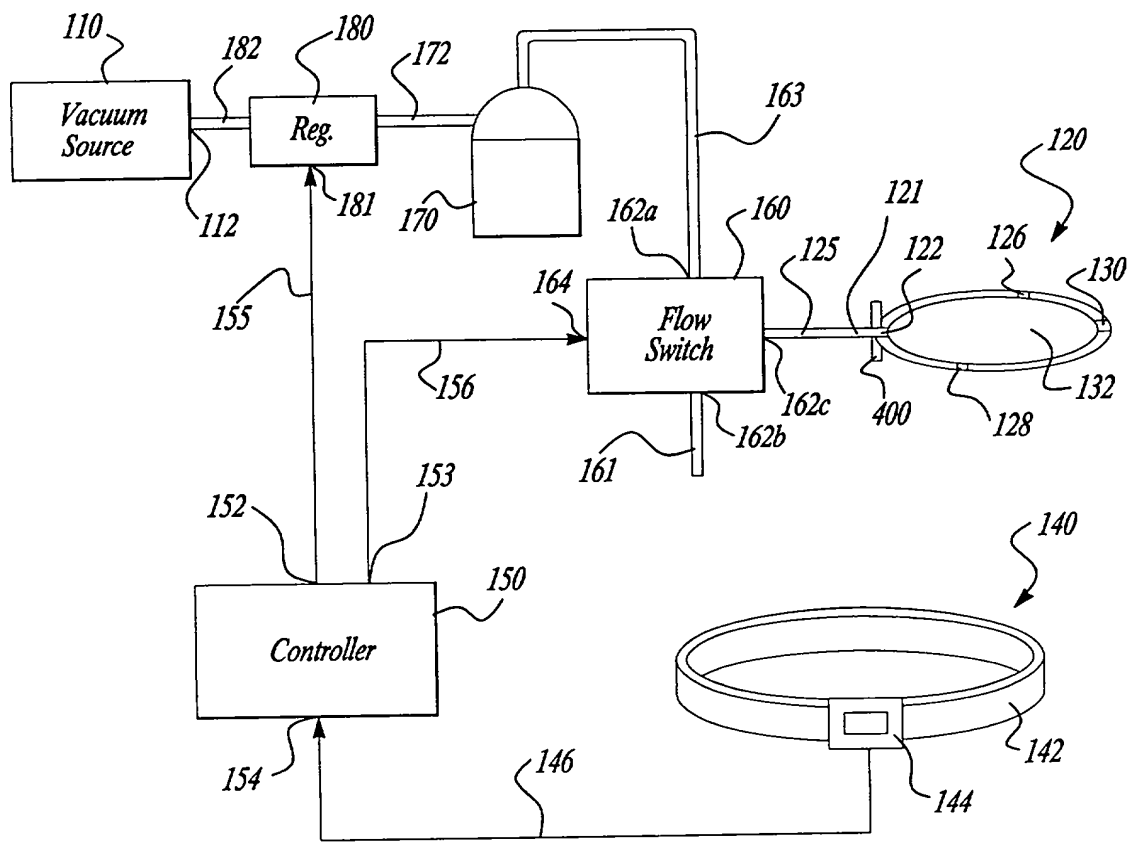


Fig-1

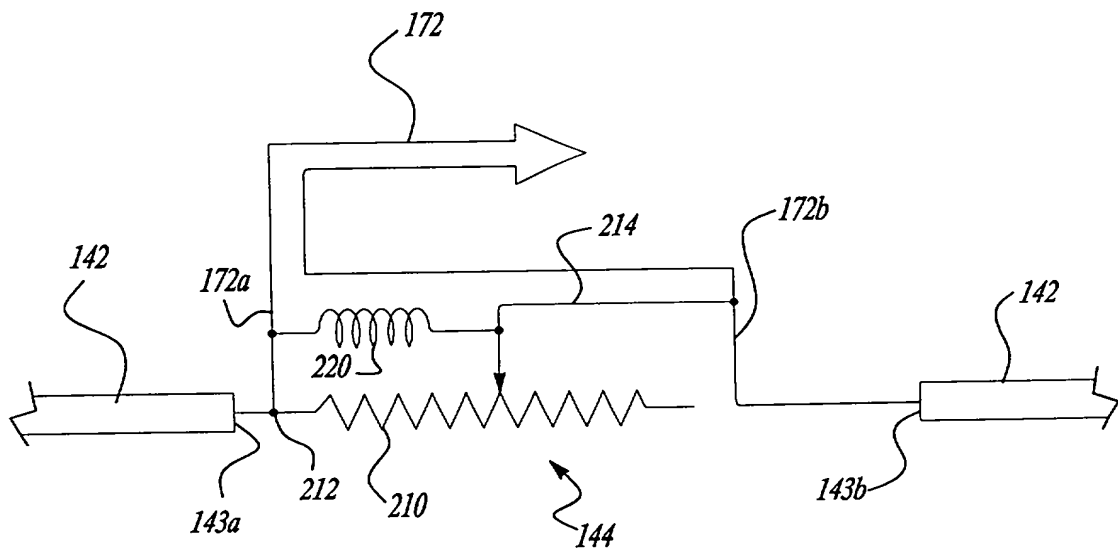
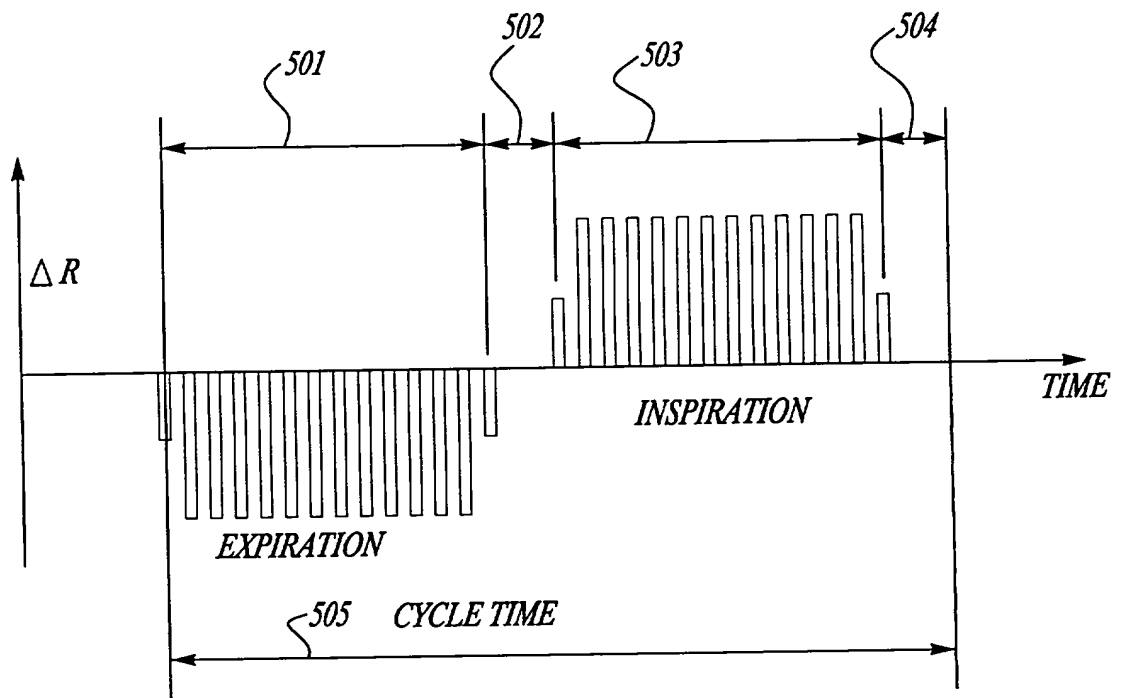
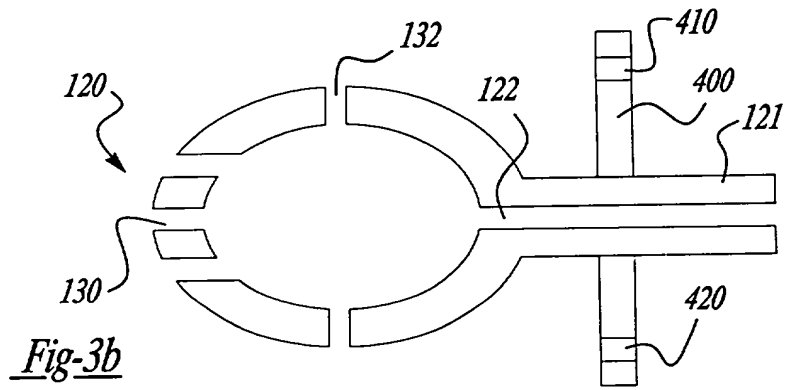
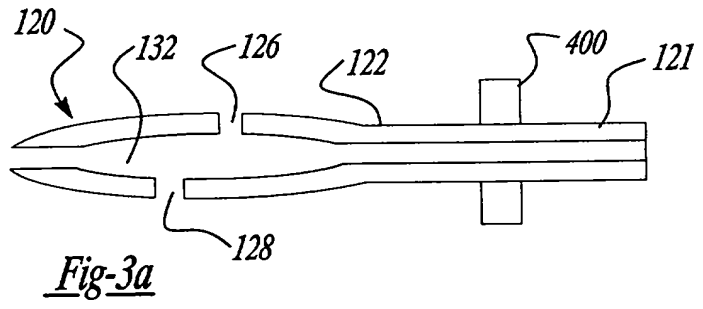


Fig-2



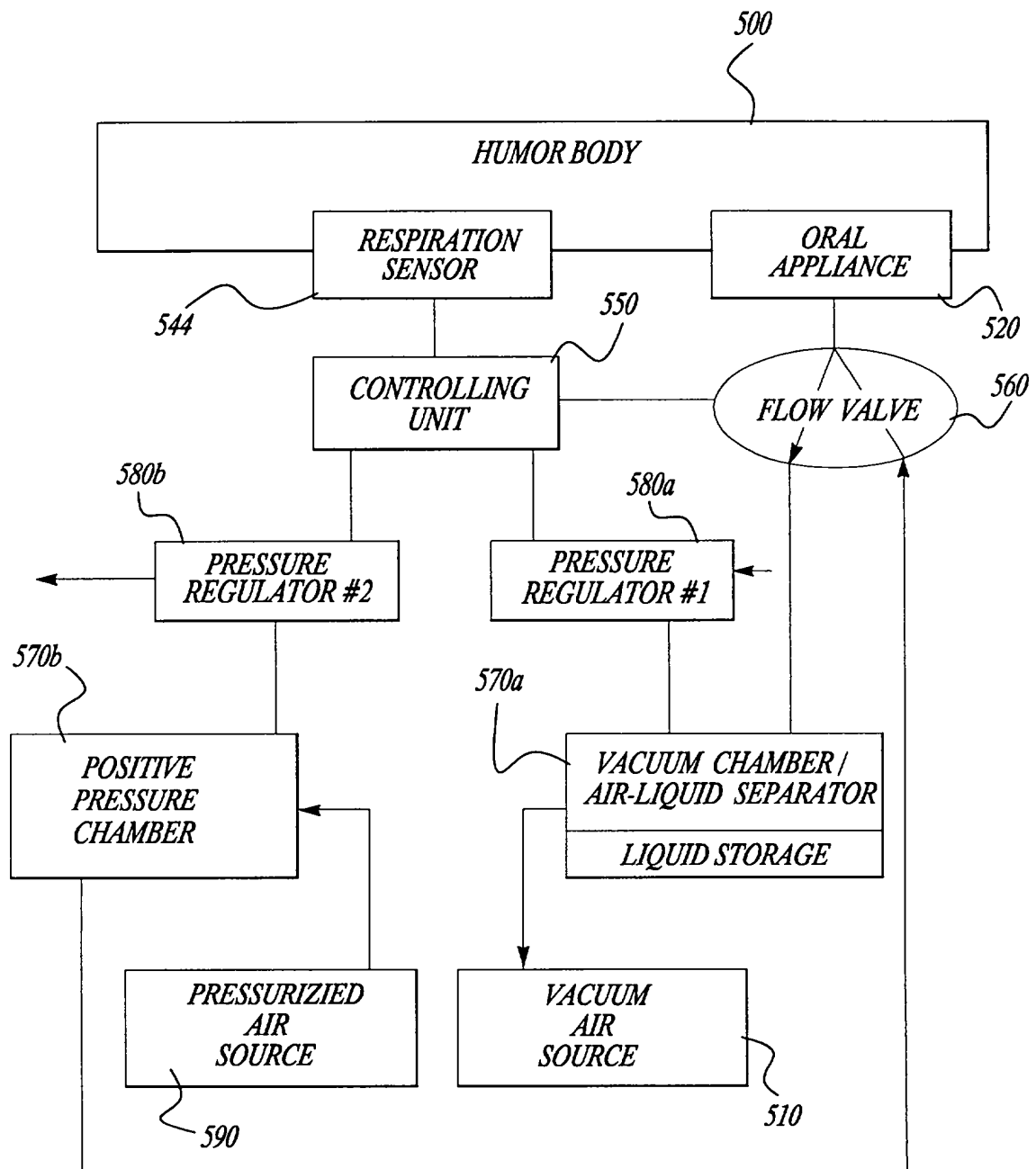


Fig-5